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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/820,403	04/08/2004	Taka-Aki Sato	0575/65823-A	8435

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EXAMINER	
WESSENDORF, TERESA D	

ART UNIT	PAPER NUMBER
1639	

DATE MAILED: 11/04/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/820,403	SATO, TAKA-AKI	
	Examiner	Art Unit	
	T. D. Wessendorf	1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 July 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13 and 16-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13 and 16-20 x* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of Claims

Claims 1-13 and 16-20 are pending and under examination.

Claims 14-15 have been cancelled.

Specification

The objection to the specification because of minor informalities has been obviated with the amendments/corrections to the specification.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112, first paragraph

Claims 1, 3, 10-13 and 16-20, as amended, are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention for reasons advanced in the last Office action.

Response to Arguments

Applicants state that the experiments discussed the proteins may have additional components (for example, oligonucleotide, mRNA, DNA and sugar) complexed therein. There is nothing particularly unpredictable about the complexing of

the additional components (that is, oligonucleotide, mRNA, DNA or sugar).

In reply, mere statements or arguments by applicants do not replace evidence either in the disclosure or prior art. Applicants have not provided in the specification or any prior art teaching of the complexing of the structurally different compounds to the protein to result in a biochemical protein-protein interaction. The method of such complex formation is not described in the specification, as of the filing date. Applicants have not described in complete and specific terms the complex formation of the structurally different compounds, e.g., mRNA, sugar for a protein -protein interaction to occur.

Applicants state that claim 16 is similar to claim 1 except that the first protein replaced by a first polypeptide comprising a PDZ domain, and (b) the second protein is replaced by a second polypeptide which comprises an amino acid sequence (s/T)-X-(V/I/L)-COOH. The term "polypeptide" is well understood in the art to include proteins as well as other molecules including multiple peptides. The discussions in the experiments support the polypeptide-polypeptide interaction (as well as protein-protein interaction). The precise configuration of the polypeptide is not important other than that the first polypeptide comprises a PDZ domain and that the second

polypeptide comprises an amino acid sequence (S/T)-X-(V/I/L)-COOH since these portions of the respective polypeptides are central to the interaction.

In response, a polypeptide as well understood it the art does not include a protein. Rather, the protein includes a polypeptide. As applicants stated above, a polypeptide within the description context, is nothing more than a protein. There is no description of a polypeptide that is different from the only disclosed protein to differentiate one from the other. The specification appears to teach that protein and polypeptide is one and the same thing. A written description of an invention involving a chemical genus, like a description of a chemical species, requires a precise definition, such as by structure, formula [or] chemical name of the claimed subject matter sufficient to distinguish it from other materials. University of California v. Eli Lilly and Col, 43 USPQ 2d 1398, 1405(1997), quoting Fiers V. Revel, 25 USPQ 2d 1601m 16106 (Fed. Cir. 1993). See also University of Rochester v. G.D. Searle & Co., 68 USPQ2d 1424 (DC WNY 2003).

Claims 1-13 and 16-20, as amended, rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a

way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. [This is a new matter rejection].

The claimed method wherein at least one array is complexed to any one of oligonucleotide, mRNA and sugar is not supported in the as-filed specification. The original specification does not describe a single complex. It is not apparent as to how such complexed between the proteins and the different structurally compounds are made. Applicants state that the Examples disclose such complex. However, there is nothing in any of the Examples which describes a complexed formation. MPEP 71.02 clearly states that applicants point out where support (by page and line numbers) can exactly be found in the specification.

Claim Rejections - 35 USC § 112, second paragraph

Claims 1, 3, 10-13 and 16-20, as amended, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for reasons set forth in the last Office action.

Response to Arguments

1. Applicants assert that by the Amendment, claims 10-13 and 17-20 have been amended to clarify that the oligonucleotide, mRNA, DNA or sugar is complexed to the first protein or first polypeptide in an array element.

In reply, the amendment does not obviate this rejection as it is not clear how each of the structurally different elements e.g., sugar is complexed i.e., the manner it is ocmplexed to a protein to form a protein-protein interaction. The as-filed specification does not provide a definition for said complexed (formation).

2. Applicants state that by the amendment to claim 3, the rejection has been overcome.

In reply, the amendment to claim 3 has not obviated the rejection. Claim 3 does not contain any screening. It is not clear how one or more drug targets is screened by a method drawn to steps of making.

3. Applicants state that regarding the difference between claim 1 and claim 16, the term "polypeptide" (as mentioned above) is well understood in the art to include proteins as well as other molecules including multiple peptides. Therefore, claim 16 clearly encompasses additional subject matter not covered by claim 1. Further, applicants incorporate herein, the discussion above.

In response, as stated above, as well known in the art, a protein includes a polypeptide and not the other way around. Thus, the specification, at the time of filing, does not provide a distinguishing characteristic between the two compounds and appear to claim only a protein.

Claim Rejections - 35 USC § 103

Claims 1-9 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Doyle (Cell) in view of any one of applicant's disclosure of known prior art or Schneider-Mergener (Comparative and Functional Genomics) or Harris et al (Jrnl. of Cell Science) for reasons of record.

Response to Arguments

Applicant maintains the claimed invention is patentable over Doyle, Schneider and Harris for at least the following reasons. The subject application describes high-throughput and low cost methodologies for preparing protein (or polypeptide) arrays based on biochemical interaction between proteins (or polypeptides). Applicant found (through experimentation, such as described in the application) that polypeptide which comprises an amino acid sequence (S/T)-X-(V/I/L)-COOH is particularly suitable in binding another polypeptide which comprises a PDZ domain. Applicant does not find teaching or suggestion in the Schneider- Mergener paper that the interaction between a

polypeptide which comprises an amino acid sequence (S/T)-X-(V/I/L)-COOH and another polypeptide which comprises a PDZ domain can be harnessed for preparing polypeptide arrays. Harris survey contemporaneous research domains, including in particular the mechanism and domains in signaling complex assembly. Applicant does not find teaching or suggestion Harris that the interaction between a polypeptide which comprises an amino acid sequence (s/T)-X-(V/I/L)-COOH and another polypeptide which comprises a PDZ domain can be harnessed for preparing polypeptide arrays which keep the polypeptides in a functionally active state and allow, example, multiple drug screenings under physiological conditions.

Applicant does not dispute that array technology has recently been used to facilitate high-throughput experiments. However, although each of the Doyle paper, the Schneider-Mergener paper and the Harris paper describes bits and pieces of the background art, none of the cited art embodies the recognition that the interaction between polypeptide which comprises an amino acid sequence (s/T)-X-(V/I/L)-COOH and another polypeptide which comprises a PDZ domain can be harnessed for preparing polypeptide arrays, as provided by independent claims 1 and 14- 16.

In response, applicant's arguments in harnessing the elements to form an array are unclear i.e., as to how the elements are harnessed. Furthermore, the combined teachings of the prior art are not bits and pieces combinations. Rather, a positive disclosure, if not at least a suggestion, as to why one having ordinary skill in the art at the time of the invention can arrive to the instant claimed invention by applying knowledge clearly present in the prior art. Doyle discloses, page 1067, a modular PDZ domain that binds to the peptide motif T/S-X-Val at the C-terminus of protein K Channels and NMDA receptor ion channels. Doyle further discloses at page 1072 that Val can be varied with Ile. Doyle does not disclose a method of preparing an array for the PDZ domain with its receptor. Harris et al disclose an array of target proteins to which PDZ containing proteins bind to. Thus, whether in array form or not, the interaction between the PDZ domain and peptide motif is known in the art. To harness this interaction in an array form as taught by e.g., Schneider would provide the motivation to one having ordinary skill in the art at the time of invention. Applicant does not dispute that the well-known array technology has been used to facilitate high-throughput experiments. Thus, the combined teachings of the prior art would have led one

having ordinary skill in the art to the claimed method, at the time the invention was made.

Double Patenting

Claims 1-9 are rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-8 of prior U.S. Patent No. 6,743,630 for reasons of record.

Response to Arguments

Applicant states that the binding of the amino acid sequence (S/T)-X-IV/I/LI-COOH of the second protein to the PDZ domain of the first protein array is central to the interaction. However, the first protein itself has the advantage that many components (for example, oligonucleotide, mRNA, DNA, sugar, etc.) can be complexed to it. Similarly, many components can be complexed to the second protein. Thus, contrary to the contention of the Office Action, array does not need have a plurality of proteins.

In response, there is nothing in the specification that describes a complexed of a protein with the other structurally different elements that result in the central protein-protein interaction. Since applicant argues that the protein-protein interaction is the central interaction, it is little wonder that the specification does not describe any complexed of a protein and e.g., mRNA, sugar and DNA. [Note further that the

obviousness double patenting rejection preclude those elements complexed with the proteins].

Claims 1-9 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-8 of U.S. Patent No. 6,743,630 for reasons advanced in the last Office action.

Applicant states that it is well established that the claim term "plurality" covers two or more but not only one.

In reply, applicant's instant claim to an array albeit, reciting a protein instead of the '630 proteins do not seemed to differentiate with each other as the same, if not similar, array (which by definition contains more than one proteins i.e., plurality) is claimed.

No claim is allowed.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS

of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to T. D. Wessendorf whose telephone number is(571) 272-0812. The examiner can normally be reached on Flexitime.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (571) 272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

T. D. Wessendorf
Primary Examiner
Art Unit 1639

tdw
October 15, 2005